information collection and has assigned OMB control number 0910–0264. The approval expires on November 30, 2003. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: November 28, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–30831 Filed 12–4–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1060]

Agency Information Collection Activities; Announcement of OMB Approval; Adoption of FDA Food Code by Local, State, and Tribal Jurisdictions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Adoption of FDA Food Code by Local, State, and Tribal Jurisdictions'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 3, 2000 (65 FR 47736), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–448. The approval expires on November 30, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: November 28, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–30874 Filed 12–4–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1440]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; User Fee Cover Sheet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by January 4, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

User Fee Cover Sheet; Form FDA 3397—(OMB Control Number 0910–0297)—Extension

Under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g and 379h), the ''Prescription Drug User Fee Act of 1992'' (PDUFA) (Public Law 102–571), as amended by the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115), FDA has the authority to assess and collect user fees for certain drug and biologics license applications and supplements. Under this authority, pharmaceutical companies pay a fee for certain new human drug applications, biologics license applications or supplements submitted to the agency for review. Because the submission of user fees concurrently with applications and supplements is required, review of an application cannot begin until the fee is submitted. Form FDA 3397 is the user fee cover sheet, which is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fee submitted for an application with the actual application by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new drug applications, biologics license applications, and supplemental applications.

Respondents to this collection of information are new drug and biologics manufacturers. Based on FDA's data base system, there are an estimated 208 manufacturers of products subject to PDUFA. However, not all manufacturers will have any submissions in a given year and some may have multiple submissions. The total number of annual responses is based on the number of submissions received by FDA in fiscal year 1999. CDER estimates 2,478 annual responses that include the following: 125 new drug applications, 1,458 chemistry supplements, 755 labeling supplements, and 140 efficacy supplements. CBER estimates 443 annual responses that include the following: 8 biologics license applications, 396 manufacturing (chemistry) supplements, 29 labeling supplements, and 10 efficacy supplements. The estimated hours per response are based on past FDA experience with the various submissions, and range from 5 to 30 minutes. The hours per response are based on the average of these estimates.

In the **Federal Register** of August 18, 2000 (65 FR 50540), the agency requested comments on the proposed collections of information. No significant comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3397	208	14.4	2,921	.30	876

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 28, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–30829 Filed 12–4–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–1491, HCFA–382, and HCFA–R–207]

Agency Information Collection Activities: Submission For OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

(1.) *Type of Information Collection Request:* Extension of a currently approved collection;

Title of Information Collection: Request for Medicare Payment—Ambulance and Supporting Regulations in 42 CFR Section 410.40 and 424.124;

Form No.: HCFA–1491 (OMB# 0938–0042);

Use: This form is used by physicians, suppliers, and beneficiaries to request payment of Part B Medicare services. It is used to apply for reimbursement for ambulance services.

Frequency: On occasion;

Affected Public: Business or other for-profit, Individuals or households, and Not-for-profit Institutions;

Number of Respondents: 9,301,183;

Total Annual Responses: 9,301,183;

Total Annual Hours: 390,418.

(2.)*Type of Information Collection Request:* Extension of a currently approved collection;

Title of Information Collection: ESRD Beneficiary Selection and Supporting Regulations Contained in 42 CFR 414.330;

Form No.: HCFA–382 (OMB# 0938–0372);

Use: ESRD facilities have each new home dialysis patient select one of two methods to handle Medicare reimbursement. The intermediaries pay for the beneficiaries selecting Method I and the carriers pay for the beneficiaries selecting Method II. This system was developed to avoid duplicate billing by both intermediaries and carriers.

Frequency: Other (One time only);

Affected Public: Individuals or households, business or other for-profit, and not-for-profit institutions;

Number of Respondents: 8,600;

Total Annual Responses: 8,600;

Total Annual Hours: 717.

(3.) *Type of Information Collection Request:* Revision of a currently approved collection;

Title of Information Collection: Evaluation of the State Medicaid Reform Demonstrations and Evaluation of the Medicaid Health Reform Demonstrations;

Form No.: HCFA–R–207 (OMB# 0938–0708);

Use: These evaluations investigate health care reform in ten states that have implemented demonstration programs using Section 1115 waivers. The surveys gather information to answer questions regarding access to health care, quality of care delivered, satisfaction with health services, and the use and cost of health services. During the extended period of authorization, the surveys will be administered to Medicaid eligibles, both demonstration participants and comparison group non-participants.;

Frequency: Other: One-time;

Affected Public: Individuals or Households;

Number of Respondents: 5,050;

Total Annual Responses: 5,050;

Total Annual Hours: 2,746.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's Web Site Address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: November 20, 2000.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–30840 Filed 12–4–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1162–N]

Medicare Program; Establishment of the Advisory Panel on Ambulatory Payment Classification Groups and Request for Nominations for Members

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the establishment of the Advisory Panel on Ambulatory Payment Classification (APC) Groups and solicits nominations for members of the panel. The purpose of the panel is to review the APC groups and their associated weights and advise the Secretary and the Administrator of the Health Care Financing Administration (HCFA) concerning the clinical integrity of these groups and weights, which are major elements of the hospital outpatient prospective payment system (OPPS). This notice also announces that on November 21, 2000 the Secretary signed the charter establishing the panel. The charter will